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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,078	07/10/2003	Steven P. Schwendeman	22727/04125	3384

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CALFEE HALTER & GRISWOLD, LLP
800 SUPERIOR AVENUE
SUITE 1400
CLEVELAND, OH 44114

EXAMINER	
BETTON, TIMOTHY E	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 09/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/617,078	SCHWENDEMAN ET AL.	
	Examiner	Art Unit	
	Timothy E. Betton	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-29 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-6 are drawn to the method comprising administering a biodegradable polymeric delivery system with (a) an effective amount of one or more antigens and (b) one or more basic additives, classified in class 424, subclass 426. If this group is elected, then the below summarized specie elections are also required.

Group II. Claim 27 is drawn to an immunogenic composition for eliciting an immune response against an antigen as disclosed in relation to method steps in Group I. If this group is elected, then the below summarized specie elections are also required.

Group III. Claims 7-26 are drawn to the method comprising administering a biodegradable polymeric delivery system comprising an effective amount of a human chorionic gonadotropin (hCG), classified in class 424, subclass 426. If this group is elected, then the below summarized specie elections are also required.

Group IV. Claims 28 and 29 are drawn to an immunogenic composition for eliciting an immune response against human chorionic gonadotropin (hCG) as disclosed in relation to method steps in Group II, classified in class 424, subclass 426. If this group is elected, then the below summarized specie elections are also required.

Inventions I and II are distinct from inventions III and IV in that two distinct products and two associated methods are disclosed respectively. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are distinct in that inventions I and II are directed to practicing an immunogenic composition for eliciting an immune response against an antigen related to a method of enhancing immunogenic response thereof. However, inventions III and IV are directed to practicing an immunogenic composition for eliciting an immune response against human chorionic gonadotropin (hCG) related to a method of enhancing an immunogenic response thereof. These products and methods are related but distinct in that they are not connected in at least one of: design, operation or effect. In the instant case, these products are distinct in either design or effect. By distinctness in design, Invention I, specifically claim 1, lacks limitations regarding the exclusivity to just one antigen and to just one basic additive in comparison to claim 7 of Invention III, which discloses the limitation of (1) human chorionic gonadotropin (hCG) and (1) basic additive. By distinctness in effect, the immunogenic composition for eliciting an immune response against an antigen (Invention II, Claim 27) may reasonably invoke a significantly different initial response if it is not acting directly against a human chorionic

gonadotropin antigen and is not acting in concomitance with any other antigen as disclosed in Invention IV, Claim 28. Claim 27 lacks the limitations of Claim 28, i.e., specific ranges, ranges of ratios and direct ratios. The effects of both Inventions I and Invention III are therefore distinct. Furthermore, the Inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Invention I is distinct from Invention II. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, Invention I as claimed is drawn to a method comprising administering a biodegradable polymeric delivery system, while Invention II is drawn to the instant immunogenic composition for eliciting an immune response against an antigen as disclosed in relation to method steps in Invention I. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Invention III is distinct from Invention IV. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are

not obvious variants. See MPEP § 806.05(j). In the instant case, Invention III is drawn to a method comprising administering a biodegradable polymeric delivery system comprising an effective amount of a human chorionic gonadotropin (hCG), while Invention IV is drawn to an immunologic composition for eliciting an immune response against human chorionic gonadotropin (hCG) as disclosed in relation to method steps in Invention III. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Because these inventions are distinct for the reasons given above and there would be a serious burden on the Examiner if restriction were not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

SPECIE ELECTIONS FOR GROUPS I-IV

Immunogenic Composition Specie Elections for Groups I-IV

This application contains claims directed to the following patentably distinct species: Choose (1) immunogenic composition (polymeric delivery system) with one or a specific combination of antigens and one or a specific combination of basic additives. Further, choose (1) antigen carrier system between conjugation or encapsulation or the combination of both said antigen carrier systems as disclosed in Claim 10 for Invention III. Furthermore, choose (1) polymeric delivery system that comprises an adjuvant or

excipient as disclosed in Claims 25 and 26 respectively. The species are independent or distinct because the claims encompass a broad array of immunogenic compositions in terms of formulation. It would be an undue search burden on the Examiner because of the consideration of a myriad of therapeutic outcomes and proper criteria of success due to various factors disclosed in the direct claims.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 27 is generic to the above electable species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

SPECIE ELECTIONS FOR GROUPS I-IV

Methods Specie Elections for Groups I-IV

This application contains claims directed to the following patentably distinct species: Choose (1) method of enhancing an immunogenic response. For example, the method process of administering one or more antigens and one or more basic additives would be distinct from a method process of enhancing an immune response by administration of one specific antigen (hCG) and one specific basic additive. The species are independent or distinct because there would be distinctness in design of administration and in initial therapeutic effect/outcome. It would be an undue search burden on the Examiner because of the consideration of a myriad of therapeutic outcomes and proper criteria of success due to various factors disclosed in the direct claims.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1,2,4,5,7,10-14,17,20, and 26 are generic to the above electable species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Notice of Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process

claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy E. Betton whose telephone number is (571) 272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TEB

Ardin H. Marschel 9/6/06

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER